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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,952	09/08/2004	Cclal Albayrak	ABS0006/US	6918
33072	7590	12/13/2007		
KAGAN BINDER, PLLC SUITE 200, MAPLE ISLAND BUILDING 221 MAIN STREET NORTH STILLWATER, MN 55082			EXAMINER AUDET, MAURY A	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 12/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/506,952

Applicant(s)

ALBAYRAK, CELAL

Examiner

Maury Audet

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

Art Unit: 1654

### DETAILED ACTION

Applicant's amendment and response are acknowledged. Claim 2 has been amended into claim 1 in order to more distinctly claim the invention and address the outstanding rejections, in part. Claims 1 and 3-9 are under examination. Due to the recitation of art not previously of record, the present action is made NON-FINAL.

#### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchinson (US 5,889,110) in view of Chen et al. (US 7,081,489), Bhagwatwar et al. (US 20030049320) and Yeh et al. (US 5869103, cited by International Authority in related PCT Search Report).

Applicant has argued that the combination of references does not teach the precipitation of the active substance prior to solidification. Chen et al. is cited to remedy this deficiency, while falling within analogous art to Hutchinson and providing motivation to arrive at the claimed invention.

Hutchinson was discussed previously (see entire document). Due to the present claims amorphous language, it is still unclear whether the steps of Hutchinson, in various examples, expressly teach the "effecting precipitation" step as comprising an L 1/L2 combination wherein the latter is increased over the former (Applicant's claims 2-4). It is clear Hutchinson teach

Art Unit: 1654

L1/L2, wherein the latter is increased, following a precipitation step, and wherein the L2 is a non-solvent to the goserelin acetate (see e.g. claim 16, step iv)). This seems to be the only issue, as to whether Hutchinson expressly teaches within one of the examples this stepwise approach, or whether such would have been merely obvious. Additionally, it is not clear whether Hutchinson teach volume fraction of the aqueous surfactant solution ranges between 60 and 80% of the aqueous and organic solvents combined in step (b) (Applicant's claim 7).

Chen et al. teach making of polymeric nanoparticles comprises providing active agent nanoparticles having average diameter of 5-100 nm. The active agent nanoparticles are treated with an anionic surfactant to form modified active agent nanoparticles. The modified nanoactive agent nanoparticles are mixed with a solution of polymer in a *solvent at first temperature*, which is greater than the melting temperature of the polymer and less than boiling point of the *solvent to form a first mixture*. The mixing comprises the use of sonication. *A non-solvent is mixed with first mixture to form a second mixture*. The second mixture is sonicated to form an emulsion. The emulsion is cooled to a *second temperature at a rate effective to precipitate polymeric nanoparticles* comprising the polymer with the modified active agent nanoparticles (abstract, entire document).

As previously discussed, Bhagwatwar et al. teach a method of forming microparticles comprising the elected species of active substance goserelin acetate and polymer poly-DL-lactide-co-glycolide (e.g. para 158, claims 8, 26, 37, and 47), with any suitable solution/solvent well known in the art (e.g. para 2-5, 40, 75, entire document), and contemplating any well known microparticle size well known in the art for the use of microparticles in vivo.

Bhagwatwar et al. teach microparticles, but does not expressly teach that microparticles includes

Art Unit: 1654

the species nanoparticles and specific size ranges under 1  $\mu\text{m}$ , was not expressly found therein (e.g. Applicant's claim 11).

As previously discussed, Yeh et al. teach the formation of nano/microparticle, which comprises active substances and the polymer poly-DL-lactide-co-glycolide, including in size ranges less than 1  $\mu\text{m}$  (e.g. col. 1, col. 3, lines 35-41, entire document).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at an L1/L2 solvent mixture as part of the "effecting precipitation" step, in Hutchinson, because Chen et al. advantageously teach that the active substance is not added in solid state to the polymer solution and is formed in situ and precipitated as part of the solvent process. Hutchinson, within the analogous art, advantageously teach various steps and means of carrying out the same ultimate goal of microparticle formation comprising active substance goserelin acetate within polymer poly-DL-lactide-co-glycolide, and further in view of the advantageous teachings of Chen et al., as well as Bhagwatwar et al., using different steps to carry out the same and Yeh et al. to arrive at size limitations within that contemplated herein.

Likewise, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a volume fraction of the aqueous surfactant solution ranges between 60 and 80% of the aqueous and organic solvents in the initial mixing of the goserelin acetate-polymer poly-DL-lactide-co-glycolide of Hutchinson, in view of Chen et al., and further in view of Bhagwatwar et al. or Yeh et al., because both Hutchinson and Chen et al. advantageously teach routinely optimizable amounts of the solutions/solvents therein, as do the latter references, to carry out the desired results of the artisan and the selection of the aqueous surfactant solution

Art Unit: 1654

ranges between 60 and 80% of the aqueous and organic solvents in the initial mixing of the goserelin acetate-polymer poly-DL-lactide-co-glycolide, would have merely obvious depending on the results sought, absence evidence to the contrary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-9 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims remain rejected as unclear what "agents" (e.g. solvents) are contemplated as L1 and L2 are, such that the claimed invention has not been distinctly claimed. What distinct solvents (e.g. genus, class of solvents) must be used to carry out the invention as claimed? Applicant's arguments have been considered but are not found persuasive. Applicant has provided insufficient specification description to lend ample support to clarify this matter. Due to the uncertainty of this step and the agents, it remains unclear how L1 and L2 distinguish themselves over the art of record as discussed above. In other words, until the

Art Unit: 1654

invention is distinctly claimed (or clear specification guidance, e.g. examples provided), it is unclear what the invention is.

***Conclusion***

No claims are allowed.

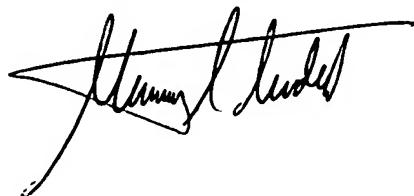
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 12/7/2007

MAURY AUDET  
PATENT EXAMINER

A handwritten signature in black ink, appearing to read 'Maury Audet', is written over the printed name and title.